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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,801	12/09/2000	David Kenneth Johnson	Johnson 60/17024	2575

7590 06/01/2005

DEANNA J. NELSON  
104 TASMAN COURT  
CARY, NC 27513

EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/733,801	Applicant(s) JOHNSON, DAVID KENNETH	
	Examiner David J. Venci	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on March 15, 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*106*

## DETAILED ACTION

### *Allowable Subject Matter*

The indicated allowability of claims 9-17 and 19 is withdrawn in view of the application of the teachings of Johnson (US 5,631,172) to Applicant's amended claims. Rejections based on the newly cited reference follow.

Claim 18 appears to remain free of the cited prior art for the reasons set forth in the prior Office Action.

### *Claim Rejections - 35 USC § 112*

Claims 9-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 9-13 and 16-17, the recitation of "chelate-fluorophore tracer composition" is indefinite because it appears that a fluorophore is not a required claim limitation. For example, if both R1 and R2 are H, then the composition does not contain a fluorophore.

In claims 9-13 and 16-18, the recitation of "p-CH<sub>2</sub>C<sub>6</sub>H<sub>4</sub>-X-Y" is indefinite. It is not clear what chemical entity or structure corresponds to the letter "p". The chemical structure of "p-CH<sub>2</sub>C<sub>6</sub>H<sub>4</sub>-X-Y" is not clear.

In claims 9-13 and 16-18, the recitation of "-HNC(S)NH-", "-NHC(O)-", and "-NH-C<sub>3</sub>N<sub>3</sub>Cl-NH-" is indefinite. It is not clear what chemical entity or structure corresponds to parentheses "(" or ")". The chemical structures of "-HNC(S)NH-", "-NHC(O)-", and "-NH-C<sub>3</sub>N<sub>3</sub>Cl-NH-" is not clear.

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In claims 9-13 and 16-17, the recitation of " $(4+m-n)$ " or " $(4-n)$ " is indefinite because it is not clear what chemical entity or structure corresponds to " $(4+m-n)$ " or " $(4-n)$ ". It is not clear what chemical entity or structure corresponds to the result of the mathematical expression " $(4+m-n)$ " or " $(4-n)$ ".

In claims 9-13, step a), the recitation of "the target metal" lacks antecedent basis.

In claims 9-11, the recitation of "whereby a positive net value... and a zero or negative net value" (emphasis added) is indefinite because it is not clear whether/how a mathematical operation simultaneously results in a positive, zero, and negative value.

In claims 9-11, step c), the recitation of "said second tracer composition being present at the same concentration as the first tracer composition" is indefinite because it is not clear whether said "first tracer composition" is also present in the second series of serial dilutions.

In claims 9-11, the recitation of "for as many non-target metals as may be required to fully define the metal selectivity" is indefinite because the algorithmic endpoint establishing a defined "metal selectivity" is not clear. A person of skill in the art cannot ascertain the standard or degree of definition required to "define" metal selectivity.

In claims 9-11, the recitation of "according to its intended purpose" is indefinite. The recitation of "its" is indefinite because it is not clear what noun(s) encompass the pronoun "its". The recitation of "intended purpose" is indefinite because it is not clear whether/how an inanimate object is capable of forming intent or having purpose. It is not clear what step(s) are required for ascertaining "its" intent or purpose.

In claims 9-11, step d), the recitations of "the non-target tracer composition" and "the target tracer composition" lack antecedent bases.

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In claims 9 and 11, step d), the recitations of "each pair of solutions", "the combinings of steps b) and c)", and "the two solutions in the pair" lack antecedent bases.

In claim 9, step a), the recitation of "an aqueous solution thought to contain said biological binding agent" is indefinite because it is not clear whether the presence of said biological binding agent in said solution is known or not known.

In claims 16-17, the recitation of "R<sub>3</sub> and R<sub>4</sub> are H, CH<sub>3</sub>, or are fused into a cyclohexyl ring system" is indefinite because R<sub>3</sub> and R<sub>4</sub> do not appear in the chemical structure.

In claim 19, the recitations of "the rabbit polyclonal antiserum" and "the EDTA-Pb complex" lack antecedent bases.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (US 5,631,172).

Johnson teaches a method for evaluating metal selectivity (see col. 5, lines 54-55, "screening assays") of a macromolecular biological binding agent (see col. 5, line 55, " monoclonal antibodies") comprising the

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steps of: combining serial dilutions (see col. 8, line 59, "antibody liter [titer]") of an aqueous solution thought to contain said biological binding agent (see col. 12, lines 11-12, "sample thought to contain... MLC-reactive antibodies") with a target chelate fluorophore tracer composition (see col. 5, lines 27-30, "chelating ligands... ethylenediaminetetraacetic acid (EDTA) and diethylenetriaminepentaacetic acid (DTPA)", see col. 5, lines 51-52, "the ligand may be covalently linked to... a label") comprising the target metal (see col. 12, lines 23-24, "The first step employs target MLC"), measuring fluorescence polarization (see col. 13, lines 59-60, "fluorescence polarization immunoassays (FPIA's) are preferred"), combining serial dilutions (see col. 8, line 59, "antibody liter [titer]") of an aqueous solution thought to contain said biological binding agent (see col. 12, lines 11-12, "sample thought to contain... MLC-reactive antibodies") with a target chelate fluorophore tracer composition (see col. 5, lines 27-30, "chelating ligands... ethylenediaminetetraacetic acid (EDTA) and diethylenetriaminepentaacetic acid (DTPA)", see col. 5, lines 51-52, "the ligand may be covalently linked to... a label") comprising a non-target metal (see col. 12, lines 36-37, "further screened for reactivity with analogous MLC of cross-reactive metals"), measuring fluorescence polarization (see col. 13, lines 59-60, "fluorescence polarization immunoassays (FPIA's) are preferred"), and repeating the foregoing for other non-target metals (see col. 12, lines 36-37, "further screened for reactivity with analogous MLC of cross-reactive metals").

With respect to step d), Johnson teaches metal-selective antibodies (see e.g. col. 12, line 46, "Lead(II)-selective antibodies"), whereby a positive net value results from subtracting non-target metal fluorescence polarization from target metal fluorescence polarization.

With respect to claims 10-11, Johnson teaches a method for screening antibodies from serum (see col. 8, line 62, "antiserum") and hybridoma supernatant (see col. 12, line 21, "hybridoma supernatant").

With respect to claims 12-13, Johnson describes an immunoassay method for determining the concentration of a target metal ion (see Abstract, "immunoassays for metal ions") in an aqueous solution (see col. 3, line 62, "water treatment plants") comprising the steps of: combining an aliquot of said

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solution with a buffered solution of EDTA or DTPA (see col. 14, line 35, "buffer salt(s) and the ligand(s)", see col. 5, lines 27-30, "Useful chelating ligands... include... ethylenediaminetetraacetic acid (EDTA) and diethylenetriaminepentaacetic acid (DTPA)"), adding a target chelate fluorophore tracer composition (see col. 5, lines 27-30, "chelating ligands... ethylenediaminetetraacetic acid (EDTA) and diethylenetriaminepentaacetic acid (DTPA)", see col. 5, lines 51-52, "the ligand may be covalently linked to... a label") comprising the target metal (see col. 14, lines 40-41, "a tracer molecule comprising the same MLC conjugated to a fluorophore", see col. 8, lines 44-45, "main group metal ions, transition metal ions or metal ions of the lanthanide and actinide series"), adding a macromolecular biological binding agent (see col. 14, lines 39-40, "a monoclonal antibody... specific for the target MLC"), measuring fluorescence polarization (see col. 13, lines 59-60, "fluorescence polarization immunoassays (FPIA's) are preferred"), and comparing fluorescence polarization values to a standard curve (see col. 14, line 50, "standard curve").

With respect to claims 14-15, Johnson describes an immunoassay method wherein the aqueous solution is extracted from a solid sample (see col. 10, line 2, "tissues") or a water sample (see col. 3, line 62, "water treatment plants").

With respect to claims 16-17, Johnson describes an immunoassay method wherein the aqueous solution is extracted from a solid sample (see col. 10, line 2, "tissues") or a water sample (see col. 3, line 62, "water treatment plants"), and the target chelate fluorophore tracer composition comprises lead (see col. 8, lines 44-45, "main group metal ions, transition metal ions or metal ions of the lanthanide and actinide series", see col. 3, line 60, "lead").

With respect to claim 19, Johnson describes an immunoassay method comprising a rabbit (see col. 8, line 54, "rabbit").

***Response to Arguments***

In prior Office Action, claims 1 and 3 (now incorporated into claims 9-13 and 16-17) were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "chelate-fluorophore tracer composition." Specifically, claims 1 and 3 were indefinite because it appeared that a fluorophore was not a required claim limitation if both R1 and R2 are H. In response, Applicant has amended the affected claims to require that "R1 must be H when R2 is p-CH<sub>2</sub>C<sub>6</sub>H<sub>4</sub>-X-Y and conversely, R2 must be H when R1 is p-CH<sub>2</sub>C<sub>6</sub>H<sub>4</sub>-X-Y" (see Applicant's Remarks, p. 22, lines 9-10). Applicant further argues that chelate-fluorophore tracer compositions are exemplified throughout the specification (see Applicant's Remarks, p. 22, lines 10-20). Applicant's arguments have been carefully considered but are not persuasive. The metal-chelated reagents of claims 9-13 and 16-17 do not require the fluorophore entity p-CH<sub>2</sub>C<sub>6</sub>H<sub>4</sub>-X-Y. For example, if both R1 and R2 are H, then the composition does not contain the fluorophore entity p-CH<sub>2</sub>C<sub>6</sub>H<sub>4</sub>-X-Y. Since the fluorophore entity p-CH<sub>2</sub>C<sub>6</sub>H<sub>4</sub>-X-Y is not required in the "chelate-fluorophore tracer composition", it is not clear what chemical entity is responsible for the "fluorophore" character of the "chelate-fluorophore tracer composition".

In prior Office Action, claims 1 and 3 (now incorporated into claims 9-13 and 16-17) were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "fused into a ring system." Specifically, claims 1 and 3 were indefinite because it was not clear whether R3 and R4 are fused into the same ring system or are each fused into a separate ring system. In response, Applicant has amended the affected claims to specify that R3 and R4 are fused into a "cyclohexyl" ring system. Applicant further argues that the cyclohexyl ring system is a single ring system and directs Examiner's attention to structure (H) of Figure 3 (see Applicant's Remarks, p. 23, lines 1-5). Applicant's arguments have been carefully considered and are persuasive. Accordingly, this rejection is withdrawn.



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**Conclusion**

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci  
Examiner  
Art Unit 1641

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05/27/05